ACADEMIC RESEARCH ENHANCEMENT AWARD

Release Date: February 11, 1999

PA NUMBER: PA-99-062

P.T.

National Cancer Institute
National Center for Complementary and Alternative Medicine
National Center for Research Resources
National Eye Institute
National Human Genome Research Institute
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Child Health and Human Development
National Institute on Drug Abuse
National Institute on Deafness and Other Communication Disorders
National Institute of Dental and Craniofacial Research
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Environmental Health Sciences
National Institute of General Medical Sciences
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke
National Institute of Nursing Research
National Library of Medicine

Application Receipt Dates: May 25, September 25, January 25

PURPOSE

The National Institutes of Health (NIH) is continuing to make a special effort to stimulate research in educational institutions that provide baccalaureate training for a significant number of the Nation's research scientists but that have not been major recipients of NIH support. Since Fiscal

Year (FY) 1985, Congressional appropriations for the NIH have included funds for this initiative, which NIH has implemented through the Academic Research Enhancement Award (AREA) program and an annual Request For Applications. Based on the expectation that funds will continue to be available each year, since 1997 the NIH invites applications for AREA grants (R15) through a standing, ongoing Program Announcement (PA).

AREA funds are intended to support new ("type 1") and ongoing ("renewal" or "competing continuation" or "type 2") health-related research projects proposed by faculty members of eligible schools and components of domestic institutions. The AREA will enable qualified scientists to receive support for small-scale research projects. These grants are intended to create a research opportunity for scientists and institutions otherwise unlikely to participate extensively in NIH programs to support the Nation's biomedical and behavioral research effort. It is anticipated that investigators supported under the AREA program will benefit from the opportunity to conduct independent research; that the grantee institution will benefit from a research environment strengthened through AREA grants and furthered by participation in the diverse extramural programs of the NIH; and that students will benefit from exposure to and participation in research and be encouraged to pursue graduate studies in the health sciences.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Academic Research Enhancement Award, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2000" at http://www.crisny.org/health/us/health7.html.

ELIGIBILITY REQUIREMENTS

Applicant Schools/Components:

All health professional schools/colleges and other academic components of domestic institutions offering baccalaureate or advanced degrees in the sciences related to health are eligible, except those that have received research grants and/or cooperative agreements from the NIH totaling more than $2 million per year (in both direct and indirect costs) in each of four or more of the last seven years. Note that this criterion of financial eligibility is based on the amount of NIH research grant monies received, not by the institution (university or college) as a whole, but by the individual school/college or aggregation of "other academic components" (see definition below)

where the principal investigator has an appointment (e.g., School of Medicine, College of Nursing, etc.). To determine the eligibility of a school or component with regard to this requirement, applicants should consult the list of Ineligible schools/components on the AREA Web page at http://www.nih.gov/grants/funding/area.htm. If the name of the school does not appear on the list, it may be eligible to apply for AREA grants.

For purposes of eligibility for the AREA program, the following definitions apply:

o "Health professional schools" (schools or colleges of medicine, dentistry, osteopathy, pharmacy, nursing, veterinary medicine, public health, optometry, allied health, and podiatry) means an accredited public or non-profit private school that provides training leading to a degree granted by that school (e.g., M.D., D.D.S., M.P.T., or equivalent degree). The term "accredited" means a school or program that is accredited by a recognized body or bodies approved for such purpose by the Secretary of Education.

o "Research grants and cooperative agreements" includes all extramural awards designated by an activity code starting with R, P, M, S, K, or U, and also G12 and D42. Scientific evaluation awards (R09, U09) are excluded.

o "Other academic components" means all schools, departments, colleges, and free-standing institutes of the institution EXCEPT the health professional schools, taken as a SINGLE component.

An applicant school/component may submit several applications proposing different research projects from different investigators.

Principal Investigator:

o May not be the principal investigator of any active NIH research grant at the time of award of an AREA grant (although he or she may be one of the project personnel for an active NIH grant held by another principal investigator).

o May not be awarded more than one AREA grant at a time (although he or she may hold successive AREA grants).

o May not submit an application to NIH for another research project grant for essentially the same project proposed in a pending AREA application (in accordance with the general NIH

prohibition against the submission in the same review cycle of more than one application for the same work).

o Is expected to conduct the majority of the research at the grantee institution, although limited use of special facilities or equipment at another institution is permitted.

Scientists working in AREA-eligible minority or women's educational institutions are encouraged to participate in this program.

MECHANISM OF SUPPORT

The R15 mechanism is used to designate applications and awards for AREA grants, to distinguish the special objectives of these grants from those of other types of NIH research grants. This award will enable scientists at eligible institutions to receive support for small research projects, either for feasibility studies, pilot studies, and other small-scale programs that would provide data preliminary to a traditional research project grant (R01) or as support for an ongoing program of research. Through this mechanism, a maximum of $100,000 in direct costs plus facilities and administrative (formerly, indirect) costs at the rate negotiated for the institution may be awarded for a period of up to three years. Allowable direct costs include salaries for the principal investigator and other research personnel (including students), supplies, equipment, travel, and other items specifically associated with the proposed research project. If necessary, a no-cost extension of up to twelve months may be requested by the institution to allow the principal investigator to finish the proposed project.

Supplemental Funding of Existing Grants

For Underrepresented Minority Students: The NIH recognizes the need to increase the number of underrepresented minority scientists participating in biomedical and behavioral research. Therefore, it is emphasizing the use of administrative supplements to existing grants in order to attract underrepresented minorities into biomedical and behavioral research. Principal investigators at domestic institutions who hold an active NIH research grant (including an active AREA grant) are eligible to submit a request for an administrative supplement to the awarding component that issued the parent grant. For the purposes of an active AREA grant, the request will be to support a minority candidate who is a high school or undergraduate student. Exceptions to this rule may be made by the awarding component that issued the AREA grant. For a full discussion of this additional funding opportunity and procedures for submitting a request

for a supplement, see the NIH Guide for Grants and Contracts, May 14, 1999 at the following Web site: http://www.nih.gov/grants/funding/funding_program.htm.

For Individuals with Disabilities: The NIH also recognizes the need to extend opportunities to individuals with disabilities who are capable of entering or resuming research careers. According to the Americans With Disabilities Act, a "disabled individual" is one who has a physical or mental impairment that substantially limits one or more major life activities, who has a record of such impairment, or who is regarded as having such impairment. Accordingly, principal investigators of an active AREA grant may also submit a request for an administrative supplement for this purpose to the awarding component that issued the parent grant. For a full discussion of this additional funding opportunity and procedures for submitting a request for a supplement, see the NIH Guide for Grants and Contracts, May 14, 1999 at the following Web site: http://www.nih.gov/grants/funding/funding_program.htm.

RESEARCH OBJECTIVES

Background

The NIH is the principal research arm of the Department of Health and Human Services (HHS). At present, 22 awarding components (known as Institutes or Centers) and several support and service Centers constitute the NIH. The NIH fosters the development of new knowledge in the biomedical and behavioral sciences, the ultimate goal of which is to combat disease and improve the health of mankind. To achieve its goals, the NIH conducts research in its own laboratories and clinics and it funds research conducted in research and academic institutions throughout the world by means of grants, cooperative agreements, and contracts. The majority of grantees are academic institutions, but other organizations (including for-profit organizations) participate significantly in NIH-supported research. The NIH provides funds for research projects, research training, career development of new and established scientists, and research and medical library resources.

Research grants represent the largest proportion of all NIH extramural awards. The research plan for each research grant application is generated and developed by an investigator referred to as the "principal investigator." On behalf of the investigator, the institution submits the grant application to the NIH for consideration for support. Principal investigators of NIH grant applications are most frequently affiliated with universities or medical schools, and most hold doctorate degrees. Requirements for who may be a principal investigator on an application (e.g., tenure-track status, citizenship status, etc.) are those of the institution, not NIH .

The NIH has long used a dual peer review system for the evaluation of applications. This system, which has a statutory base, ensures that only the most meritorious and relevant proposals are considered for funding. The first level of review involves panels composed primarily of non-Federal experts, referred to as scientific review groups (SRGs) or "study sections" that are organized according to scientific areas. These panels of experts render an impartial review and evaluation of each application. They consider not only the scientific merit of a proposal, but also the background and experience of the principal investigator, the research facilities available for the project, and the appropriateness of the direct costs requested.

The second level of review is conducted by the National Advisory Council or Board of the awarding component to which the application is assigned. These groups, composed of scientists, physicians, and laypersons who are leaders in public affairs, are chosen for their expertise, interest, or activity related to the awarding component's mission. The council or board will take into account the relevance of the goals of the project in relation to the mission of the awarding component, program balance, and the availability of funds.

The Center for Scientific Review (CSR), a component of the NIH, receives all grant applications submitted to the NIH, assesses each one for relevance to the health mission of the NIH; and assigns those that are acceptable to the appropriate Scientific Review Group (SRG) for initial scientific merit review, and to the appropriate NIH awarding component for consideration for an award.

The AREA program and its application, review, and award procedures have been developed within this established framework for NIH grant-supported research activities.

Research Objectives of the NIH Institutes and Centers

AREA grants will support small-scale, new or ongoing health-related research projects, including pilot research projects and feasibility studies; development, testing, and refinement of research techniques; secondary analysis of available data sets; and similar discrete research projects that demonstrate research capability. Listed below, by awarding component (Institute or Center) are the research topics of particular interest to the Institute/Center under the AREA program. Listed in the INQUIRIES section is the AREA program representative for each of the participating Institutes and Centers; a potential applicant is encouraged to contact the person listed for the Institute(s) or Center(s) with interest in the applicant's proposed topic for additional scientific program information and for pre-application guidance.

The research objectives of the AREA program are those of the individual NIH Institutes and Centers, as follows:

National Institute on Aging (NIA)

The NIA is interested in, and has responsibilities for, aging research that includes fundamental studies of biological processes, including studies of aging at the molecular, organelle, cellular, organ, and organ system levels; the interaction of aging and diseases of aging; biomedical and psychosocial factors in maintaining health\ and effective functioning in the middle and later years, relevant social and behavioral relationships; and research that broadens the base of knowledge underlying adequate health services for the aging and the aged. The Institute is interested in normal physiological and biochemical changes with aging, involving areas such as immunology, neurobiology, endocrinology, nutrition, and exercise physiology, as well as clinical diseases and disorders of aging such as Alzheimer's disease, osteoporosis, osteoarthritis, falls, and urinary incontinence. The Institute also has responsibility for research concerned with the biological, social, psychological, cultural, and economic factors that affect both the process of growing old and the status and roles of older people in society. Under this broad mandate, health and wellbeing are viewed as the outcome of complex biological, physiological, medical, psychological, and socioenvironmental processes.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

The NIAAA supports basic and applied research on mechanisms of action of alcohol on biobehavioral processes and effects of alcohol on the mind and body. Support is available to develop new knowledge in a wide range of areas relevant to alcohol abuse and alcoholism; biochemical, physiologic, and behavioral mechanisms leading to pathologic drinking behavior; alcohol-induced organ damage; and clinical, behavioral, and epidemiological studies that will lead to more effective diagnosis, prevention, and treatment. The NIAAA supports alcohol-relevant research involving all of the life-science disciplines.

National Institute of Allergy and Infectious Diseases (NIAID)

The objective of NIAIID's research program is to acquire the knowledge which will eventually lead to the treatment and prevention of infectious, allergic, and immunologic diseases. The Institute's overall strategy of attacking the array of problems on a broad front relies on free-ranging research in microbiology and includes the following research problem areas: isolation, characterization,

and biology of disease-causing microbes; antibiotic or drug resistance among bacteria, viruses, and parasites; development of successful and safe antimicrobial compounds, particularly for viruses and parasites; and new approaches to understand and manipulate the immune system.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

The NIAMS supports basic and clinical studies related to the rheumatic diseases and to diseases and disorders of connective tissue, bone, and skin. Areas of research include: inflammation, infectious agents and genetic factors related to rheumatic diseases; structure and function of cartilage and connective tissue; arthritis in children; systemic lupus erythematosus; rheumatoid arthritis; - osteoarthritis; spondylitis and related syndromes; gout and pseudogout; the structure and function of skeletal muscle; bone structure, formation, degradation and repair; osteoporosis; biomaterials, biomechanics, and joint replacement; inherited connective tissue diseases; bone immunology and transplantation; metabolism of epidermis, dermis and subcutaneous fat; immunologically mediated cutaneous disorders; photobiology, photoallergy, and phototoxic reactions; vitiligo; psoriasis, bullous diseases of the skin; and acne.

National Cancer Institute (NCI)

The NCI is the Federal Government's principal agency for cancer research and control. Programs of the NCI focus on: (1) cancer etiology including laboratory, field, and epidemiologic and biometric research on the cause and natural history of cancer and means for preventing cancer, as well as studies on the mechanisms of cancer induction and promotion by chemicals, viruses, and environmental agents; (2) cancer biology and diagnosis research in the areas of cell biology, immunology, molecular biology, developmental biology, biochemistry, genetics, and pathology; (3) cancer treatment research in the areas of drug development, biological response modifiers, and radiotherapy development, including diagnostic imaging and clinical trials for curing or controlling cancer; and (4) cancer prevention and control research, development, technology transfer, demonstration, and education and information dissemination programs to expedite the use of new information relevant to prevention, detection, and diagnosis of cancer and pretreatment evaluation, treatment, rehabilitation, and continuing care of cancer patients.

National Institute of Child Health and Human Development (NICHD)

The goal of NICHD's research programs is the improvement of maternal, infant, and child health through support of basic and clinical research to elucidate normal and abnormal growth, development, and maturation, from gametogenesis through maturity. To this end, NICHD

supports research in: reproductive biology, chemistry, and medicine; fertility regulation; contraceptive development and evaluation; perinatology, pregnancy, and labor; developmental and clinical ge netics; developmental biology; developmental neurobiology; developmental and reproductive immunology; birth defects; population dynamics; developmental endocrinology; social, cognitive, and affective development; and the biological bases of behavioral development.

The NICHD also supports biomedical and behavioral research on mental retardation and developmental disabilities; pediatric, adolescent, and maternal HIV infection and AIDS; and, in the context of its National Center for Medical Rehabilitation Research, NICHD also supports the development of medical, behavioral, psychological, social, and technological interventions designed to optimize functioning after impairment, disability, or handicap.

National Institute on Deafness and Other Communication Disorders (NIDCD)

The NIDCD supports biomedical and behavioral research related to the normal and disordered processes of hearing, balance, smell, taste, voice, speech and language. Basic and clinical studies are encouraged of genetic, molecular, cellular, physiological, biochemical, and behavioral aspects of function in health and disease. The Institute also supports research concerned with disease prevention, health promotion and the special biomedical and behavioral problems associated with communication impairments and disorders.

National Institute of Dental and Craniofacial Research (NIDCR)

The mission of the NIDR is the advancement of knowledge concerning the oral-facial complex in all of its aspects. This includes the conduct and support of research into the etiology, epidemiology, prevention, diagnosis, and treatment of such dental diseases as caries and periodontal disease; increasing our knowledge about craniofacial development and malformations; studies of various oral soft tissue diseases, including herpes and oral cancer; and increasing knowledge about orofacial pain and other oral sensory and motor dysfunctions. Cutting across these oral disease or dysfunction areas are research activities in such areas as salivary glands and secretions, mineralization and fluorides, tooth pulp biology, nutrition, behavioral studies, and research related to dental implants, replants, and transplants and to dental restorative biologically comparable and derived materials.

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

The NIDDK conducts and supports research focused on a number of diseases that are characterized by chronicity and long-term disabling effects. Areas of interest include: diabetes, cystic fibrosis, and other errors of metabolism; diseases of the gastrointestinal tract, including the liver and gallbladder; endocrine disorders; diseases of the blood; kidney and urological diseases, and studies of nutrition and nutrition-related disorders. NIDDK's responsibilities in these areas encompass investigations of etiology, pathogenesis, diagnosis, and treatment.

National Institute on Drug Abuse (NIDA)

The research programs of the NIDA are devoted to increasing the understanding of the causes and consequences of drug abuse, as well as to developing effective treatments and treatment systems. This goal is accomplished by support of extramural research projects that improve and refine the methods for the assessment, treatment and prevention of drug abuse. The scientific studies supported are broad and include: fundamental studies on the mechanisms of action of abused drugs; biochemical strategies for identifying and developing successful drug abuse treatment agents; behavioral and clinical pharmacology; services research; epidemiology, natural history and prevention of drug abuse; treatment research; community-based research on reduction of drug-taking behaviors; and studies of drug abuse as a contributing factor in the AIDS epidemic.

National Institute of Environmental Health Sciences (NIEHS)

The NIEHS is the principal Federal agency for biomedical research on the effects of chemical, physical, and biological environmental agents on human health and well-being. The Institute supports research and training focused on the identification, assessment, and mechanism of action of potentially harmful agents in the environment. Research results form the basis for preventive programs for environmentally-related diseases and for action by regulatory agencies. The NIEHS, thus, has responsibility for providing knowledge to assist in societal decisions involving current and future chemicals, processes, and other factors which may have impact on human health either directly or indirectly by altering man's environment. This responsibility mandates efforts toward a thorough understanding of the early manifestations and the mechanism of human disease brought about by toxic agents and the development of more accurate and more rapid methods to predict and assess the toxicity of such agents.

National Eye Institute (NEI)

The mission of the NEI is to gain new knowledge concerning the normal functions of the eye and visual system and the pathology of visual disorders. Working to this end, the NEI supports research and research training aimed at improving the prevention, diagnosis, and treatment of visual disorders and fosters research in the rehabilitation of the visually handicapped. Both laboratory and clinical research are funded under the following major NEI programs: Retinal and Choroidal Diseases; Corneal Diseases; Cataract; Glaucoma; Strabismus, Amblyopia and Visual Processing. Within each program, research ranges from attempts to elucidate the fundamental biological processes that underlie disease to the development and clinical testing of new diagnostic and therapeutic techniques.

National Institute of General Medical Sciences (NIGMS)

The NIGMS supports non-disease-targeted research in the basic biomedical sciences. Research areas of interest include biophysics, cell biology, molecular biology, genetics, pharmacology, and those areas of chemistry which have relevance to biomedical problems. The emphasis is on understanding basic biological mechanisms, particularly at the cellular, subcellular, and molecular levels.

National Heart, Lung, and Blood Institute (NHLBI)

The NHLBI supports basic and clinical research pertaining to the structure, function, and diseases of the cardiovascular, pulmonary, and blood systems. The Institute's research program also includes transfusion medicine and blood resources. The NHLBI carries out its mission through a number of research programs that provide support for projects ranging from studies at the molecular level to whole body studies in man and animals. Examples of research areas supported by the Institute include atherosclerosis, hypertension, cerebrovascular disease (directed at the dependent variable of blood, heart, or blood vessel), coronary heart disease, peripheral vascular diseases, arrhythmias, heart failure, and shock, congenital and rheumatic heart diseases, cardiomyopathies and infections of the heart, circulatory assistance, structure and function of the lung, chronic obstructive lung diseases, pediatric pulmonary diseases, occupational and immunologic interstitial lung diseases, respiratory failure, pulmonary vascular diseases, bleeding and clotting disorders, disorders of the red blood cell, sickle cell disease, and blood resources.

National Human Genome Research Institute (NHGRI)

The NCHGR is currently engaged in a research program designed to characterize the human genome and the genomes of selected model organisms. This research program has the following interrelated goals: the construction of high resolution genetic linkage maps; the development of a variety of physical maps; the determination of the complete nucleotide sequence of the DNA of selected organisms; the development of the capability for collecting, storing, distributing, and analyzing the data produced; and the development of appropriate new technologies to achieve these goals. This project will develop a series of resources that will be available to the research community to facilitate both basic research and the application of the knowledge gained to the prevention, diagnosis, and therapy of disease.

National Institute of Mental Health (NIMH)

The NIMH exerts leadership on behalf of the Nation's mentally ill citizens by creating a firm scientific foundation for the clinical care of mental disorders; by developing and assessing innovative approaches to diagnosis, treatment, and prevention of mental illnesses; and by exchanging information nationally and internationally with all relevant individuals and organizations to improve the state of mental health knowledge and its application. The NIMH conducts and supports an integrated program of basic and clinical research and research training in biology, neuroscience, epidemiology, and psychology and other behavioral sciences, as well as services research on the organization, administration, and financing of mental health services and service systems. These studies include theoretical, laboratory, epidemiologic, clinical, methodologic and field research on well and ill human subjects and populations of all ages, and on animals where appropriate to the research questions.

National Institute of Neurological Disorders and Stroke (NINDS)

The NINDS serves as the focal point at the NIH for research on the nervous system, including cerebrovascular disease (when the dependent variable is the nervous system), the neuromuscular apparatus, and the special senses of touch and pain.

National Institute of Nursing Research (NINR)

The NINR supports research on the biological and behavioral aspects of critical health problems that confront the Nation. According to its broad mandate, the Institute seeks to reduce the burden of illness and disability by understanding and easing the effects of acute and chronic illness; to improve health-related quality of life by preventing or delaying the onset of disease or slowing its progression; to establish better approaches to promoting health and preventing disease; and to

improve clinical environments by testing interventions that influence patient health outcomes and reduce costs and demand for care. The NINR is interested in studies containing innovative ideas and sound methodologies in all aspects of nursing research consistent with its mission. Examples of areas of special interest include effects of life threatening illnesses; management of symptoms associated with specific diseases or illnesses such as diabetes, chronic wounds that fail to heal, transplantation and mechanical ventilatory support; telehealth and bioengineering interventions to address clinical problems; effects of life threatening illnesses such as asthma, traumatic brain injury, and stroke; prevention or reduction of risk factors, particularly in young children and adolescents; prevention of low birth weight; interactions among genetic factors, environment, and life style; developmental issues related to life-stage transitions; and health of minorities and other underserved populations.

National Library of Medicine (NLM)

The objective of NLM's research program is the support of investigations related to the generation, organization, and utilization of health knowledge. Such support may involve: (1) medical informatics research, a branch of investigation of the fundamental issues of health knowledge communication vis-a-vis advanced computer technologies; (2) research in health science librarianship and information science; or (3) assistance for the preparation and publication of scientific works in the health area.

National Center for Complementary and Alternative Medicine (NCCAM)

"The general purposes of the National Center for Complementary and Alternative Medicine (NCCAM) are the conduct and support of basic and applied research, ... research training, ... and other programs with respect to identifying, investigating, and validating complementary and alternative treatment, diagnostic, and prevention modalities, disciples and systems" (P.L. 105-277). In order to meet this mandate, NCCAM supports research and training programs that increase our knowledge of, and improve research methods on, complementary and alternative medicine. NCCAM supports all types of research including basic, clinical, epidemiological and health services.

National Center for Research Resources (NCRR)

The NCRR administers programs that develop and ensure the availability of resources essential to the efficient and effective conduct of human health-related research. NCRR programs are primarily institutional in nature but, while support is generally in the form of resource grants, the

NCRR makes awards for support of projects which contribute to improvement of the capability of resources to serve biomedical research. The following are research areas appropriate to the NCRR interests: (1) Research and Development in Instrumentation and Specialized Technologies for Biomedical Research. This encompasses instruments, devices, and processes to facilitate research in blomolecular and cellular structure and function. (Instrumentation includes mass spectrometry, nuclear magnetic resonance, electron spin resonance, equipment for fast kinetic research, X-ray diffraction, electron microscopy, and flow cytometry.) The application of computer science, computer engineering, and biomedical engineering to biomedical research problems is also of interest. (This includes knowledge engineering, information technology, computer graphics, image processing, computer modeling and simulation, task dedicated computer systems, and development of implantable microsensors and transducers.); (2) Research in Laboratory Animal Sciences. (This includes the etiology, pathogenesis, and control of laboratory animal diseases, as well as the environmental requirements of laboratory animals.); and (3) Development of Biomedical Research Methods Employing Lower Organisms, Tissues/Cells in Culture, or Mathematical and Computer Simulations.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994, and are available on the Web at the following URL address: http://www.nih.gov/grants/guide/notice-files/not98-024.html.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://www.nih.gov/grants/guide/notice-files/not98-024.html.

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

The PHS 398 (rev. 4/98) is the form to be used to apply for an AREA grant. The form may be downloaded from the NIH Home Page at http://www.nih.gov/grants/forms.htm. It is also available at most institutional offices of sponsored research, or it may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892-7910, telephone: 301/435-0714, email: GrantsInfo@nih.gov. The PHS 398 application kit contains instructions on submission procedures, "Section II. Submitting Your Application" (pp. 21-22), that must be observed by AREA applicants. Also included in the application kit are "General Instructions" (pp. 5-6) and "Specific Instructions" (pp. 6-20) for completing the application; these must be adhered to, except where they have been modified by the following Supplemental Instructions.

Supplemental Instructions

As AREA grants are one of the mechanisms included in NIH's Modular Grants initiative, applicants must observe the supplemental instructions for modular grant applications contained in the Notice published in the NIH Guide for Grants and Contracts on December 18, 1998 (http://www.nih.gov/grants/guide/notice-files/not98-178.html). Briefly, the features of modular grants related to application preparation include: the requirement that direct costs be requested only in modules of $25,000, the omission of information on detailed budget categories and on pending "Other Support," and the inclusion in the "Biographical Sketch" of information on related research projects in which key personnel are currently participating or have participated. Some of the "just in time" aspects of modular grants (e.g., the omission of detailed budget information) have been in effect for AREA applications for several years.

Under modular grant procedures and the limits of a maximum length of award of three years and maximum direct costs of $100,000, there are 14 possible budget request combinations:

Length of Project	Total Direct Costs Requested	Direct Costs Requested for Year 1	Year 2	Year 3
One year	$ 25,000	25,000	-	-
	50,000	50,000	-	-
	75,000	75,000	-	-
	100,000	100,000	-	-
Two years	$ 50,000	25,000	25,000	-
	75,000	50,000	25,000	-
	"	25,000	50,000	-
	100,000	50,000	50,000	-
	"	75,000	25,000	-
	"	25,000	75,000	-
Three years	$ 75,000	25,000	25,000	25,000
	100,000	50,000	25,000	25,000
	"	25,000	50,000	25,000
	"	25,000	25,000	50,000

The specific instructions below refer to those items in the PHS 398 application form where the information requested, following from the Modular Grant initiative or the AREA program requirements, either has been modified or should not be provided at submission although the information may be requested after initial review by the NIH awarding component if there is a likelihood that the application will be funded. (The page numbers in parentheses refer to the pages in the application kit where instructions on the item appear.)

GRANT APPLICATION - Face Page (AA)

Item 2 -- Check the "YES" box and enter "Academic Research Enhancement Award" as the title. Do not enter a Number. (Page 6)

Item 6 --The entire proposed project period must not exceed three years.

(Page 9)

Item 7a --This amount must be requested in modules of $25,000. (Page 9)

Item 7b --This amount comprises the Modular Direct Costs requested in item 7a. plus Facilities and Administrative (F&A) costs (at the institution's negotiated rate) for the initial budget period. (Page 9)

Item 8a --This amount must be requested in modules of $25,000 and must not exceed $100,000; thus, the entire total direct costs of an AREA grant may only be one of four specific amounts: $25,000; $50,000; $75,000; or $100,000. (Page 9)

Item 8b -- -This amount comprises the Modular Total Direct Costs requested in item 8a. plus F&A costs for the entire budget period. (Page 9)

DETAILED BUDGET FOR INITIAL BUDGET PERIOD - (Form Page 4-DD):
Do not submit this page. It is not required, nor will it be accepted at the time of application. However, NIH may request this information just prior to award. (Page 11)

BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT - (Form Page 5-EE):
Do not submit this page as presented in the application kit. Instead, a Budget Justification page must be submitted (for samples, see http://www.nih.gov/grants/funding/modular/modular.htm), where the total modular direct costs for the entire project period should be entered on the first line and the total modular direct costs requested for each year of the project on the second line. This must be followed by a Narrative Budget Justification as follows:

- Under Personnel, name all key project personnel (salaried or unsalaried), indicate their role on the project and the percent effort of each, and provide a narrative justification of their role and percent effort. No individual salary information should be provided.

o The students who will be involved in the research should be included here. If they have not yet been individually identified, the number and academic level of those to be involved should be provided. Since a primary objective of the AREA program is to support investigators at undergraduate institutions that provide training in the sciences, principal investigators are encouraged to include students in the proposed research to the extent practicable.

- If there are any Consultants for the project, provide their names, organizational affiliations, and the services they will perform.

- Under Consortium/Contractual costs, if requested, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount.

- If there is any variation in the number of modules requested, provide additional narrative budget justification in explanation.

BIOGRAPHICAL SKETCH - (Form Page 6-FF):
The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel. No more than three pages may be used for each person. A sample biographical sketch may be viewed at: http://www.nih.gov/grants/funding/modular/modular.htm

For each key person, include within the three-page limit both the information required per the instructions on the Form plus information on the ongoing or completed research projects they have participated in during the last three years (for each, their role/responsibilities on the project, the overall goals, principal investigator, and funding sources). (Page 13)

For the principal investigator only, provide information on his or her: (a) experience in supervising students in research, and (b) other relationships within the institutional framework (e.g., cross-departmental research collaborations). This information, while it will not be used in the assessment of the scientific merit of the application, will be used in making final funding decisions. (Page 13)

OTHER SUPPORT - (Format Page 7-GG):
Do not submit this page. However, the Biographical Sketch for each of the key personnel should include information on the other projects that the person is working on or has worked on that are relevant to the proposed project (see above).

RESOURCES - (Form Page 8-HH) (Page 14)

In addition to the information requested on the Form, under "Other," provide the following information which, while it will not be used in the assessment of the scientific merit of the application, will be used in making final funding decisions:

o a profile of the students of the applicant school/academic component and any information or estimate of the number who have obtained the baccalaureate degree and gone on to obtain an academic or professional doctoral degree in the health-related sciences since 1986;

o a description of the special characteristics of the school/academic component that make it appropriate for an AREA award, where the goals of the AREA program are to: (1) strengthen the research environment of schools that are not research intensive; (2) expose students in such environments to research, and (3) provide support for meritorious research.

o a description of the likely impact of an AREA award on the principal investigator and the school/academic component. How will the AREA award strengthen the research environment of the school/academic component? How will the AREA award expose students to research?

o a statement of institutional support for the proposed research project (e.g., release time, other support, matching funds, etc.).

CHECKLIST (II):
This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. It is important to identify all exclusions that were used in the calculation of the F&A costs for the initial budget period and all future budget years. (Page 19)

PERSONNEL REPORT (JJ):
Do not submit this page. Instead, this information should be provided in the Narrative Budget Justification (see above). (Page 20)

REVIEW CONSIDERATIONS

AREA applications are reviewed by scientific review groups administered by the NIH Center for Scientific Review (CSR) and are evaluated for scientific and technical merit according to standard NIH peer review procedures, as described above (see Background). Applications will be assigned on the basis of established Public Health Service referral guidelines. As part of the initial merit review, a streamlined review process, which is employed for the review of most NIH

research grant applications, may be used. Under this process, reviewers are asked to identify the upper half of applications. These applications are discussed at the review group meeting and receive a "priority score" ranging from "best" (100) to "average" (300), while the lower half of applications are normally not discussed nor given a priority score. Nevertheless, all applicants will receive a summary statement, which will consist of the written critiques of two or more of the reviewers participating in the review group meeting.

The review schedule that will apply to AREA grant applications is as follows:

	Cycle I	Cycle II	Cycle III
Postmark Dates for:			
- AIDS-Related Applications	May 1	Sep 1	Jan 2
- All Other AREA Applications:	Jan 25	May 25	Sep 25
Scientific Merit Review:	Jun/Jul	Oct/Nov	Feb/Mar
Advisory Council Review:	Sep/Oct	Jan/Feb	May/Jun
Earliest Project Start Date:	Dec	April	July

Review Criteria: In carrying out the scientific and technical merit review of AREA applications, the scientific review group will base its recommendation and score (if the application is scored) on the overall impact of the application on its field of study by considering the following review criteria:

(1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition, all applications will also be evaluated with respect to the appropriateness of the budget, the inclusion of children, minorities, and women in clinical research projects, the procedures for the protection of animal or human subjects, and the adequacy of protections for research personnel from biohazards. Further information about these considerations is available at: http://www.csr.nih.gov/guidelines/proc.htm.

While it will not enter into the recommendation and score for an application, an assessment will be made by the review group of each application with respect to the special programmatic features of AREA grants (i.e., the suitability of the applicant School/academic component for an AREA award in terms of the extent to which it fits the goals of the AREA program, the likely availability of well-qualified students, the evidence that students have in the past or are likely to pursue careers in the biomedical and behavioral sciences; the likely impact of an AREA award on the School/academic component in terms of strengthening the research environment and exposing students to research; and the extent of the principal investigator's experience in supervising students in research. This assessment, which will be documented in an administrative note in the summary statement for the application, will be used in the second level of review by Institute program staff and by National Advisory Councils in making recommendations for funding.

AWARD CRITERIA

AREA grants are awarded on a competitive basis. Funding decisions on individual applications will be based on the proposed research project's scientific merit as evaluated in the initial scientific merit review and its relevance to NIH programs, and on the applicant institution's contribution to the undergraduate preparation of doctoral-level health professionals. Thus, after the initial scientific-technical review, applications receive a second-level review by the National Advisory Council of the Institute or Center to which the application has been assigned for potential funding. In conformance with the spirit of the House Committee Report 98-911 (to accompany H.R. 6028, HHS Appropriations for FY 1985), special consideration will be given in the funding decision process to applications from those "smaller, less prominent, four-year, public and private colleges and universities which provide undergraduate training for a significant

number of our nation's research scientists but which have not shared adequately in the growth of the NIH extramural program."

NIH implements this directive through the following policy: Among projects of essentially equivalent scientific merit and program relevance, preference will be given to those submitted by institutions that have granted baccalaureate degrees to 25 or more individuals who have obtained academic or professional doctoral degrees in the health-related sciences since 1986. In addition, funding decisions will take into account those aspects of the application that pertain to the appropriateness of and likely impact on the school/academic component and principal investigator of an AREA grant.

Both annual Progress Reports and a Final Progress Report will be required of all AREA grantees.

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions potential applicants may have is welcomed. For inquiries of a scientific nature, potential applicants should contact the Program Contact persons for the Institutes whose scientific interests are closest to those of the proposed research (see Research Objectives section above). The Program Contacts for the Institutes and Centers are:

National Institute on Aging
Dr. Miriam Kelty
Associate Director, Office of Extramural Affairs
7201 Wisconsin Avenue, Room 2C218
Bethesda, MD 20892-9205
Phone: (301) 496-9322
FAX: (301) 402-2945
E-mail: mk46u@nih.gov

National Institute on Alcohol Abuse and Alcoholism
Dr. Laurie Foudin
Division of Basic Research
6000 Executive Boulevard, Suite 402
Bethesda, MD 20892-7003
Phone: (301) 443-0912
Fax: (301) 594-0673

E-mail: lf29z@nih.gov

National Institute on Allergy and Infectious Diseases
Mr. Al Czarra
Director, Office of Program Coordination and Operations
Division of Extramural Activities
Solar Building, Room 3C28
Bethesda, MD 20892
Phone: (301) 496-7291
Fax: (301) 402-0369
E-mail: ac20a@nih.gov

National Institute of Arthritis and Musculoskeletal and Skin Diseases
Dr. Steven J. Hausman
Deputy Director
Building 31, Room 4C32
Bethesda, MD 20892-2350
Phone: (301) 402-1691
Fax: (301) 480-6069
E-mail: sh4lg@nih.gov

National Cancer Institute
Dr. Robert Hammond
Associate Director for Program Coordination
Division of Extramural Activities
Executive Plaza North, Suite 600
Bethesda, MD 20892-7405
Phone: (301) 496-2378
Fax: (301) 402-0956
E-mail: rh53k@nih.gov

National Institute of Child Health and Human Development
Dr. Susan Streufert
Office of the Deputy Director
6100 Executive Blvd., Room 4A01
Bethesda, MD 20892-7510
Phone: (301) 435-6856

Fax: (301) 402-4083
E-mail: ss149n@nih.gov

National Institute on Deafness and Other Communication Disorders
Dr. Rochelle Small
Division of Human Communication
Executive Plaza South, Suite 400-C
Bethesda, MD 20892-7180
Phone: (301) 402-3464
Fax: (301) 402-6251
E-mail: rs105f@nih.gov

National Institute of Dental and Craniofacial Research
Dr. Norman S. Braveman
Assistant Director for Program Development
Building 45, Room 4AN-24
Bethesda, MD 20892-6401
Phone: (301) 594-2089
Fax: (301) 480-8318
E-mail: nbl0u@nih.gov

National Institute of Diabetes and Digestive and Kidney Diseases
Dr. Walter S. Stolz
Director, Division of Extramural Activities
Building 45, Room 6AS-25C
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National Institute on Drug Abuse
Dr. Teresa Levitin
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Fax: (301) 443-0538

E-mail: tl25u@nih.gov

National Institute of Environmental Health Sciences
Dr. Jerrold Heindel
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Research Triangle Park, NC 27709
Phone: (919) 541-0781
Fax: (919) 541-2843
E-mail: jhl90f@nih.gov

National Eye Institute
Dr. Ralph J. Helmsen
Research Resources Officer
Executive Plaza South, Suite 350
Bethesda, MD 20892-7164
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E-mail: rh27v@nih.gov

National Institute of General Medical Sciences
Dr. Norka Ruiz Bravo
Deputy Associate Director for Extramural Activities
Building 45, Room 2AN-32K
Bethesda, MD 20892-6200
Phone: (301) 594-3910
Fax: (301) 480-1852
E-mail: Ruizbran@nigms.nih.gov

National Heart, Lung, and Blood Institute
Dr. Ronald Geller
Director, Division of Extramural Affairs
6701 Rockledge Drive, Room 7100
Bethesda, MD 20892-7922
Phone: (301) 435-0260
Fax: (301) 480-3460
E-mail: rg33k@nih.gov

National Human Genome Research Institute
Dr. Bettie J. Graham
Chief, Research Grants Branch
Building 38A, Room 610
Bethesda, MD 20894
Phone: (301) 496-7531
Fax: (301) 480-2770
E-mail: bg30t@nih:gov

National Institute of Mental Health
Henry Khachaturian, Ph.D.
Office of Science Policy and Program Planning
National Institute of Mental Health
6001 Executive Boulevard, Room 8208 MSC 9667
Bethesda, MD 20892-9667
Telephone: (301) 443-4335
FAX: (301) 443-3225
Email: hkhachat@mail.nih.gov

National Institute of Neurological Diseases and Stroke
Dr. Joseph S. Drage
Training and Special Programs Officer
Federal Building, Room 1016
Bethesda, MD 20892-9190
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Fax: (301) 402-4370
E-mail: jd66x@nih.gov

National Institute of Nursing Research
Dr. Hilary Sigmon
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Bethesda, MD 20892-6300
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Fax: (301) 480-8260
E-mail: hs38k@nih.gov

National Library of Medicine
Dr. Milton Corn
Division of Extramural Programs
Building 38A, Room 5N505
Bethesda, MD 20894
Phone: (301) 496-4621
Fax: (301) 402-0421
E-mail: rd57e@nih.gov

National Center for Complementary and Alternative Medicine
Dr. Richard L. Nahin
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Building 31, Room 5B36
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E-mail: NahinR@od.nih.gov

National Center for Research Resources
Dr. Louise E. Ramm
Deputy Director
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Bethesda, MD 20892-5662
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Fax: (301) 402-0006
E-mail: lr34m@nih.gov

Questions regarding eligibility, policies, procedures, and other administrative aspects of the NIH AREA program should be referred first to the Office of Sponsored Programs at the educational institution. Issues that remain after consultation with the institutional Office of Sponsored Programs and that are not addressed in these AREA Program Guidelines may be directed to:

Dr. Janet M. Cuca
NIH AREA Coordinator
Office of Extramural Research
National Institutes of Health
6701 Rockledge Drive, Room 6192
Bethesda, MD 20892

Phone: (301) 435-2691
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E-mail: jc55g@nih.gov

These Program Guidelines and other information related to the AREA program are available on the AREA Web page at: http://www.nih.gov/grants/funding/area.htm.

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.390. Awards are made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158; 42 USC 241 and 285) and administered in accordance with the PHS Grants Policy Statement and Federal regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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